Kaczmarek, Chris

From: Taub, Cynthia <CTaub@steptoe.com>
Sent: Thursday, October 24, 2013 9:59 AM
To: Talbert, Stephanie (ENRD) (Stephanie.Talbert@usdoj.gov)
Cc: Goldberg, Seth; Allison_Starmann@americanchemistry.com; Kaczmarek, Chris; Ross, Philip
Subject: 158W Settlement Questions
Attachments: 158W Settlement Crosswalk (2).pdf

Stephanie-

Thank you for the outline of proposed steps regarding Part 158 W that you provided on September 25. As we discussed, we compared the proposed steps with the list of issues we had provided in August and had a number of questions about which issues would be addressed by EPA's proposed actions. Per your request, attached is a "crosswalk" between the documents that lists our questions. As you will see, we took our August 9 list of proposed topics and added in bold below each topic an assessment of whether the topic appeared to be addressed by any of the proposed actions in EPA's September 25th list. We trust the attached provides sufficient information to prepare for the meeting between ACC and EPA, including AD officials. We hope to hear your proposed times for a meeting very soon.

Sincerely,

Cynthia

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SETTLEMENT COMMUNICATIONS

Crosswalk Between ACC's August 9 List of Issues and EPA's September 25 List of Proposed Actions

October 24, 2013

Appeal of 40 CFR Part 158 Subpart W
Proposed Settlement Meeting Topics and Schedule

First Meeting: Food-Related Issues. Proposed Time Frame: August 19 – 30

1. Timing and content of guidance on what is a food use and availability of Use Site Index, if separate. Will there be an opportunity to comment?

   This issue appears to be addressed by the Antimicrobial Use Site Index and possibly the first regulatory action. Please confirm.

2. What types of products will be subject to either tolerances or "408" reviews?

   This issue appears to be addressed by the Antimicrobial Use Site Index and possibly the first regulatory action. Please confirm.

   How will those be conducted and how do they differ from what EPA currently does?

   This issue does not appear to be addressed, although it might be included within item 1 of the first regulatory action. Please confirm whether this issue will be addressed, and if not, why not.

3. Differentiation of direct and indirect food uses.

   This issue appears to be addressed by the Antimicrobial Use Site Index and possibly the first regulatory action. Please confirm.

4. Applicability of new requirements to inert ingredients.

   This issue does not appear to be addressed, although it might be included within item 1 of the first regulatory action. Please confirm whether this issue will be addressed, and if not, why not.

5. What are the residue chemistry requirements, what guidance should be used in meeting them and how they will be used in risk assessments?

This issue does not appear to be addressed, although it might be included within item 3 in first regulatory action. Please confirm whether this issue will be addressed, and if not, why not.

6. How will the footnote in PRIA 3 waiving fees for newly-required tolerances be implemented?

   This issue appears to be addressed by the third bullet, "PRIA3 interpretation". Please confirm.

7. Explanation and, if necessary, correction of 200 ppb threshold value.

   This issue does not appear to be specifically addressed, although it could be included within item 3 in the first regulatory action. Please confirm whether this issue will be addressed, and if not, why not.

Second Meeting: Down the Drain (Ecotox and Environmental Fate), Implementation Issues, and Risk Assessment. Proposed Time Frame: September 9 – 20

1. **Down the Drain Issues**

   a. To what uses will new tests apply? What test material should be used?

      This issue could be addressed in items 2 and 3 of first regulatory action. Please confirm.

   b. What are the triggers for higher tier ecotox and environmental fate requirements?

      This issue does not appear to be addressed. Please confirm whether this issue will be addressed, and if not, why not.

   c. How is the EEC to be calculated for antimicrobials?

      This issue could be addressed in item 3 of first regulatory action. Please confirm.

   d. How will EPA use these new data?

      This issue does not appear to be addressed. Please confirm whether this issue will be addressed, and if not, why not.

   e. How will these data requirements be phased-in?

      This issue could be included in bullet 2, the implementation letter. Please confirm.

f. Timing and content of implementation guidance. Will there be an opportunity to comment?

This issue appears to be addressed by bullet 2, the implementation letter.

2. Implementation Issues

a. Timing and content of implementation guidance. Will there be an opportunity to comment?

This issue appears to be addressed in bullet 2, the implementation letter.

b. How will new data requirements be imposed on both new applications and existing registrations? Particularly for new "food" and "surface residue" assessments.

This issue could be included the implementation letter. Please confirm.

c. How will EPA handle inert ingredient tolerances and "food clearances" that are not tolerances? Differentiation of data requirements between actives and formulated products.

This issue could be included in the implementation letter. Please confirm.

d. When/how will EPA provide guidance for performing residue deposition and dissipation work?

This issue could be addressed in items 1 and 3 of first regulatory action. Please confirm.

3. Risk Assessment

a. How will the data required under the new rule be used in risk assessments? Registrants and applicants should be able to duplicate EPA's analysis to know how their products will be viewed, especially for new "food," ecotox and environmental fate requirements.
b. What training is being given to staff?
c. Is there guidance on risk assessment and, if not, when will there be?
d. How does EPA plan to ensure transparency in risk assessment process?

None of the risk assessment issues above appear to be addressed by any of the proposed implementation or regulatory actions. Please confirm whether these issues will be addressed in any of the implementation or regulatory actions, and if not, why not.

Third Meeting: Treated Articles, Technical Corrections and Food Follow up. Proposed Time Frame: September 23 – October 4

1. What treated articles or uses will be subject to "food" reviews? How does EPA plan to implement that in labels? How will revised labeling be phased-in?

   These issues do not appear to be addressed but could be included in bullet 1, use site index. Please confirm whether these issues will be addressed, and if not, why not.

2. How will 200 ppb threshold be calculated? What will the substance of those reviews look like and how will those reviews differ from non-food treated articles? Under what circumstances will EPA perform or use non-dietary ingestion data?

   These issues do not appear to be addressed, but could be included in regulatory action 2. Please confirm whether these issues will be addressed, and if not, why not.

3. Definition of fungicide as it applies to materials preservatives and other non-public health products.

   This issue is not specifically addressed, but may be part of regulatory action 2. Please confirm whether this issue will be addressed, and if not, why not.

Fourth and Subsequent Meetings: Topics and dates to be decided as appropriate.